

**REMARKS**

Reconsideration and allowance of the subject patent application are respectfully requested.

The specification has been amended to include headings.

Claims 8, 9 and 28 have been amended to address the informalities identified on page 2 of the office action.

Claims 31 to 35 have been canceled without prejudice or disclaimer.

Claims 1-5, 8-16 and 18-30 were rejected under 35 U.S.C. Section 102(b) as allegedly being "anticipated" by Walker et al. (U.S. Patent No. 6,302,844). While not acquiescing in this rejection, claim 1 has been amended so that it even further distinguishes over Walker et al. In particular, claim 1 now specifies that the patient's device includes a display which displays both data representing a patient's physiological condition as measured by a physiological data acquisition unit, and also a message related to the patient's condition. The feature of the display is recited in original (now-canceled) claim 12.

Claim 1 as amended further recites that "the system is adapted to analyze the data automatically with reference to known trends for the patient and in response automatically to generate and display on said display said message related to the patient's condition." The feature of displaying a "message related to the patient's condition" is based on, but not limited to, the description of an example embodiment at page 4, line 13. The feature that the data is analyzed with respect to previous known trends for the patient is based on, but not limited to, the description of an example embodiment at page 10, lines 6 and 7 which say "... the data is analyzed and may be compared with previous data, e.g. known trends. The comparison can be with data for that patient ...". The fact that the data analysis is particular to the patient is described by the paragraph at page 13, lines 4 to 12. This section mentions the automatic data analysis to spot trends for individual patients and that this analysis is "tuned to each patient's characteristics".

With respect to Walker et al., it can be readily noted from Figure 1 of this document that the patient's telemetry device 120-1 lacks a display. Unsurprisingly, therefore, Walker also lacks the idea that the patient should be shown a message relating his/her current condition to known trends for that patient. In fact, Walker et al. concentrates to a great extent on the physician end

of the system, this being largely the subject of columns 7 through 22 and does not particularly address the issue of "self-management" by the patient, which is what the claim 1 system is designed to promote. Thus, Walker et al. is typical of many prior art systems which tend to disempower the patient. Applicant's technology empowers the patient to understand and monitor their own condition (though of course with the data being sent to a server for parallel monitoring by a clinician). This empowerment is good for patients and encourages them to utilize the system. Further, this sense of control actually improves the patient's psychological state and, over the long term, improves their physical health.

Claims 1-5, 8-16 and 18-35 were rejected under 35 U.S.C. Section 102(b) as allegedly being "anticipated" by Blants et al. (U.S. Patent No. 6,231,519).

Among other things, Blants et al. lacks automatic transmission of the data to the server and also lacks adaptation of the analysis to personal trends of the patient. Moreover, it lacks the display of a message to the patient based on that personalized analysis. In essence, Blants et al. is interested in utilizing patients as monitors of air quality, see column 5, lines 60 to 62 which say: "the individuals 310 with asthma would thus form a living network of measurement devices." The lack of any personalized analysis and display to the patient means that there is no empowerment of the patient.

Claims 1-5, 8-13, 18-23 and 28-30 were rejected under 35 U.S.C. Section 102(b) as allegedly being "anticipated" by Schultze et al. (U.S. Patent No. 6,443,890).

Schulze et al. lacks any display to the patient of his/her current condition compared to known trends for that patient. Instead, Schultze et al. is concerned with a relatively invasive multi-parameter monitoring system, but the idea that the patient's measurements are compared to his/her trends, and a corresponding display made to the patient is lacking. Again Schulze et al. is characteristic of the prior art which concentrates on the provision of data to the physician rather than empowering patients to self-manage their condition.

Haller et al. (U.S. 2002/0052539) is cited in connection with the claim 6 and 7 features of a GPRS and a 3G network and Baker Jr. et al. (U.S. Patent No. 5,853,364) is cited in connection with the claim 17 feature of a Kalman smoother. Among other things, these references do not remedy the deficiencies of Schultze et al. or Walker et al. with respect to claim 1, from which claims 6, 7 and 17 depend.

The remaining dependent claims are believed to patentably distinguish from the applied references at least by virtue of their dependencies.

The features recited in the example embodiments provide a particular benefit in assisting patients in self-management of their condition. In particular, none of the prior art proposals provide, for example, immediate and real time delivery of data from the patient to the server with immediate automatic processing comparing that data to trend data for that patient, with an immediate display of a message to the patient indicating their condition. This real-time operation includes "intelligent" analysis of the data (e.g., comparing the data to trends appropriate for that patient, rather than generalized thresholds).

None of the many prior proposals for e-health systems are currently in mainstream use. The applicant provides a system which patients are prepared to use on a day-to-day basis. This is particularly important in the case of chronic conditions such as asthma and diabetes. Further, the applicant's technology tries to promote self-management of the patient's condition. Good self-management not only eases the current burden on the health services (by reducing the involvement of clinicians) but also improves the long-term health of the patients. This was emphasized in the UK Government Wanless report of February 2004 entitled "Securing Good Health for the Whole Population" (available at the UK Department of Health website and copy attached for the Examiner's convenient reference) which said that "people need to be supported more actively to make better decisions about their own health" and that "the health services must evolve from dealing with acute problems through more effective control of chronic conditions to promoting the maintenance of good health." It was also emphasized in the UK Department of Health "National Service Framework for Diabetes" (see pages 21-23 attached).

The example embodiments take account of patient psychology by providing an immediate personalized analysis by way of relevant information to the patient. In trying to promote self-management, it is important not to encourage the patient to renege responsibility but instead to take control. The applicant's concept of a real-time loop with intelligence, e.g., personalized analysis and feedback helps the patient to do this. Prior art proposals tend to aim to reduce patient involvement, which is actually quite wrong. They have confused trying to provide ease-of-use (a good thing) with dis-involving the patient (a bad thing).

None of the prior proposals provide patients real-time feedback or systems which patients will actually use long-term. The results of the studies that the applicant has performed are that patients find the system easy and rewarding to use and that it improves their self-management. Implementations of the system can provide one or more of: ease of use and immediacy of delivery of data to the server (achieved, for example, by the use of the wireless transmitter with automatic transmission of data); immediate processing and feedback by way of message display to the patient; the feedback being personalized to the patient (e.g., compared to the patient's own trends, which takes account of natural patient-to-patient variability), thus increasing the sense of involvement of the patient; and avoiding a great burden on the healthcare professional (by the use of the automatic analysis and feedback to the patients).

In summary, although many proposals for wireless telemedicine systems exist, actually trying to persuade patients to use such systems, and achieving an improvement in patients' health through their use, has not been achieved. In contrast, the applicant's telemedicine system has been used in a clinical trial which demonstrated an improvement in patients' health over 9 months of use (reduction in HbA1c for type 1 diabetes patients). The results of this clinical trial have been peer-reviewed and published in the November 2005 issue of Diabetes Care (copy attached). In relation to long-term health conditions, empowering patients to self-manage their condition has now been recognized as an important factor in improving the patient's health. Patients trialing the applicant's system have commented that the ease of use, the automatic submission and analysis of results and the fast response with a message are factors which enhance their interaction with the system and their enjoyment of the system and encourage them to use it regularly. Thus this combination of features is actually significant in providing a practically useful and usable system.

New claim 36 has been added. The subject matter of this claim is fully supported by the original disclosure and the Examiner is invited to independently confirm that this is the case. Claim 36 calls for, among other things, analyzing data representing a physiological parameter of a patient automatically with reference to known trends for the patient and in response automatically generating a message related to the patient's condition, and displaying to the patient the message related to the patient's condition. For reasons similar to those discussed


above with respect to claim 1, claim 36 is believed to patentably distinguish over the applied references.

Applicant believes that this entire application is in condition for allowance and respectfully requests a notice to this effect. If the Examiner has any questions or believes that an interview would further prosecution of this application, the Examiner is invited to telephone the undersigned.

Respectfully submitted,

**NIXON & VANDERHYE P.C.**

By:

A handwritten signature in cursive script, appearing to read "Michael J. Shea", is written over a horizontal line.

Michael J. Shea  
Reg. No. 34,725

MJS:dbp  
901 North Glebe Road, 11th Floor  
Arlington, VA 22203-1808  
Telephone: (703) 816-4000  
Facsimile: (703) 816-4100